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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/382,561 08/25/99 SUTTON A 263742002800

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EXAMINER

LOVERING, R

ART UNIT

PAPER NUMBER

1712

12

DATE MAILED:

03/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/382,561

Applicant(s)

SUTTON ET AL

Examiner

LOVERING

Group Art Unit

1712

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P r i d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on DEC 1, 2000.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

- ☒ Claim(s) 20-30 is/are pending in the application.
- Of the above claim(s) 30 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 20-29 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 20-30 are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☒ received in Application No. (Series Code/Serial Number) 08/487,420.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 246
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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DETAILED ACTION

1. Claim 30 is withdrawn from further consideration by the examiner, 37 CAR 1.142(b) as being drawn to a non-elected species. Election was made **without** traverse in Paper No. 11.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

3. Claims 20 and 22-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,993,805. Although the conflicting claims are not identical, they are not patentably distinct from each other because the stated claims herein read on, or at least overlap, the claims of the '805 patent.

4. Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,993,805 in view of Goldberg et al 4,671,954.

Claim 21 herein differs from the claims of the '805 patent in reciting that the therapeutic or diagnostic agent is the sole component of the microcapsule, but it would have been obvious to one skilled in the art at the time applicants' invention was made to substitute an immunoglobulin

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for the serum albumin in the composition of the claims of the '805 patent with full expectation of success, since Gollberg et al. (col. 3, line 36-44) disclose the interchange ability of these proteins or polypeptide^S_X as micro sphere or microcapsule-forming materials, official notice being taken of the fact that immunoglobulins are therapeutic agents.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26-29 are indefinite and incomplete in depending upon canceled claim 1. It is believed that claims 26-29 should dependent upon claim 20.

7. Applicants should update the status of 08/487,420 (now U.S. Patent No. 5,993,805) in their insertion on page 1, line 4 of the specification, said insertion having been made by a ⁶⁻proamendment filed November 15, 1999.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

9. Applicants are required to provide the publication date (at least the year) of the Maulding article, document No. 12 on applicant's IDS filed March 22, 2000.

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10. The remaining references listed on the attached forms PTO-1449 (9 sheets) and form PTO-892 are cumulative to the references applied herein, and/or further show the state of the art.

11. Any inquiry concerning this communication should be directed to Examiner Lovering at telephone number (703) 308-0443.

Lovering/dh

March 15, 2001

Richard D. Lovering
RICHARD D. LOVERING
PRIMARY EXAMINER
GROUP ~~1200~~ 1700